Department of Veterans Affairs
M-2, Part VI
Veterans Health Services and
Chapter 8
Research Administration
Washington, DC 20420
March 20, 1990

1. Transmitted is a revision to Veterans Health Services and Research Administration Manual M-2, "Clinical Affairs," Part VI, "Pathology Service," Chapter 8, "Autopsy Services." Brackets have not been used to indicate the changes.

2. Chapter 8 has been updated to:

a. Expand quality assurance in anatomic pathology affecting the monitoring of autopsy records and transmittal of findings to the staff.

b. The uses of autopsy specimens for research have been more clearly defined to clarify the right of the patients.

3. **Filing Instructions**

Remove pages	**Insert pages**
vi	delete chapter 8
8-i through 8-ii	
31 through 34	
8-1 through 8B-1	

4. **RESCISSIONS:** M-2, part VI, chapter 8, change 59, dated February 13, 1981, and VHS&RA Circular 10-88-122.

JOHN A. GRONVALL, M.D.

Chief Medical Director

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CHAPTER 8. AUTOPSY SERVICES

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RESCISSIONS

The following material is rescinded:

a. **Manuals**

M-2, Part VI, Chapter 8, change 59

b. VH&RA Circulars

10-88-122

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CHAPTER 8. AUTOPSY SERVICES

8.01 STATEMENT OF POLICY

All VA medical centers will provide autopsy services. The availability of these services will be made known to the family of each decedent and the medical staff will attempt to secure authorization for autopsy examination in all deaths.

a. The Chief of Staff is responsible to the Director for overall management of autopsy services since several services in the medical center are involved. The scope of this management includes arrangements for securing autopsy authorizations, provision of sufficient competent staff for the examinations and for timely completion of autopsy reports, maintenance of suitable facilities and appropriate coordination with funeral directors and local authorities. These responsibilities also include ensuring that autopsy findings become a continuing component of the medical center's internal monitoring of medical practice. Findings on all autopsies will be presented to the medical staff on a regular basis as expeditiously as possible. Such reviews will occur with the frequency appropriate to the level of activity in the medical center but at least once each quarter.

b. The Chief, Laboratory Service, is responsible for the professional aspects of autopsy examination, including performance of the autopsy, diagnoses, preparation of appropriate protocols and reports, retention and disposition of gross autopsy tissues (blocks, microscopic slides) and professional support of clinical and administrative activities related to the autopsy. The custody of bodies consigned to the autopsy suite resides with the Chief, Laboratory Service.

c. There will be legal authorization by the next of kin for autopsy in all instances before any prosection is begun except as provided in 38 CFR 17.155. Whenever possible, the physician responsible for the care of the patient at the time of death will be designated to request permission from the next of kin to perform an autopsy. The Decedent Affairs Clerk for Medical Administration Service can also provide assistance in obtaining permission for autopsy. The original copy of the authorization, SF 523, Authorization for Autopsy, or transcript of recorded telephone conversation will be filed in the deceased's medical record. Requests and authorization for autopsy examination by the next of kin will be honored provided the necessary legal requirements are met.

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d. Autopsy examination may be performed for medicolegal reasons in cases of unexpected death upon compliance with 38 CFR 17.155. (See M-2, Pt. VI, Ch. 11, "Toxicology," par. 8.03 (5)(a))

8.02 PHILOSOPHY OF AUTOPSY EXAMINATIONS

a. The autopsy is a significant instrument for continuous monitoring activity as part of the Systematic Internal Review Program of the Health Services Review Organization within each VA medical center. It confirms or establishes the cause of death and assists in determining the manner of death. The discrepancies between premortem and postmortem diagnoses can be used as a tool for making the autopsy an integral part of a quality assurance program. Quality assessment implies the quantitative evaluation of differences between pre- and postmortem findings to determine whether they fall within

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predetermined acceptable standards or permissible range. To date no acceptable range of discrepancies between pre- and postmortem diagnoses has been determined nationally.

b. The accrual of medical knowledge and the quality of medical care is dependent in large measure on the continuing flow of information from autopsy findings. The value of the autopsy has been enhanced rather than diminished by advances in diagnostic technology and remains a vital component in the assurance of good medical care. However, autopsy rates have declined markedly over the past 2 decades. Efforts to increase autopsy rates to validate medical diagnoses are long overdue.

8.03 AUTOPSY RATES AS PERCENTAGE OF HOSPITAL DEATHS

a. VHS&RA policy for autopsy rates has been revised to encourage the maximum number of autopsies on patients within a wide range of clinical categories rather than to seek a fixed autopsy rate as a percentage of all hospital deaths on randomly selected patients.

b. Patient categories, listed in paragraphs c. (1) and (2), are targeted for autopsy and are expected to yield critical information by which to judge the quality of care and premortem diagnostic accuracy in VA medical centers. A policy of substituting autopsy selection by diagnostic category rather than by prescribed percentage does not necessarily imply the autopsy rate would be low. In general medical and surgical VA medical centers, with excellent cooperation between clinicians and laboratory physicians, the rate may exceed 50 percent.

c. Any conscious selection process may introduce a bias. This factor must be considered when identifying patients for autopsy who have expired from specified categories of disease. The advantage of a conscious selection process is that it augments medical education. The disadvantage is that it detracts from the autopsy as a truly randomized quality assurance factor. True random selection of patients for autopsy eliminates this bias.

(1) **Surgical Service**

(a) Autopsy should be sought on not less than 50 percent of patients dying with a history of transplant of heart, kidney, liver, lungs, skin, or pancreas.

(b) Cardiac surgical patients who had cardiac surgery within the period of their hospital admission.

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(c) Unexpected postoperative deaths.

(d) Patients dying from postoperative complications such as, but not limited to:

1. Sepsis, shock, hemorrhage, or vascular disease.

2. Disruption of the following anastomotic connections:

a. Gastrointestinal

b. Tracheobronchial

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(e) Deaths resulting from:

1. Invasive diagnostic procedures

2. Endoscopic procedures

3. Cardiopulmonary insufficiency

4. Renal insufficiency

5. Hepatic insufficiency

6. Transfusion reaction

(f) Deaths under anesthesia

(g) Deaths following an unscheduled readmission within 14 days of discharge for the same or related surgical condition.

(2) **Medical Service**

Among patients who expire on the Medical Service wards, the medical staff should attempt to secure autopsies on not less than 50 percent of patients dying under the following circumstances:

(a) Deaths during or within 1 week from the performance of a diagnostic or therapeutic procedure such as cardiac catheterization, angioplasty, dialysis, exercise tolerance test, endoscopy, bronchoscopy.

(b) Sudden and unexpected death during hospitalization. This category refers to patients with a treatable condition or those in whom the clinical course revealed marked improvement.

(c) Death of patients on whom a diagnosis was not made in life, despite extensive clinical evaluation.

(d) Death from nosocomial infections not adequately resolved by laboratory studies or antibiotic treatment during the life of the patient.

(e) Deaths during trials of new or experimental therapeutic agents.

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(f) Autopsy to recover expensive or dangerous implanted prostheses such as automatic implantable cardioverter defibrillators, nuclear driven cardiac pacemakers, an item which could explode during cremation. When explanted at autopsy, the prostheses will be returned to the service that implanted it. If the service has no use for the prosthesis, it will be sent to Acquisition and Materiel Management Service.

(g) Death following an unscheduled readmission within 14 days of discharge for the same or related medical condition.

(h) Any patient who dies on a Medical Service ward following an organ transplant.

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(3) **Mental Health & Behavioral Sciences Service**

The medical staff should attempt to secure autopsies on not less than 50 percent of patients who expire on psychiatry bed services. Of particular interest are those patients who expire under the following circumstances:

(a) Death following unscheduled admission from VA Nursing Home Unit, Domiciliary, transfer from a state or community nursing home, from a VA psychiatric hospital to a general medical and surgical hospital or from a psychiatry bed service to a medical bed service within the same facility.

(b) Unexpected deaths.

(c) Violence to self or others (requiring consultation with the medical examiner).

(d) Patients receiving therapy with multiple pharmaceutical agents.

(4) **Neurology Service**

Among patients who expire on the Neurology Service ward, staff should attempt to secure autopsies on not less than 50 percent of patients dying under the following circumstances:

(a) Death during or within 1 week of the performance of a diagnostic or therapeutic procedure such as angiography; or a neurosurgical procedure.

(b) Death during or within 48 hours of lumbar puncture or a myelogram.

(c) Death from infectious diseases, particularly slow viral disorders such as Jakob-Creutzfeld Disease or HTLV-1 (human T-lymphotropic virus type 1). Caution should be exercised during these autopsies.

(d) Death from Alzheimer's or other dementias.

(e) Sudden and unexpected death during hospitalization.

(f) Death of patients on whom a diagnosis was not made during life despite extensive clinical evaluation.

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(g) Death during therapeutic trials of new or experimental therapy.

(h) Death following an unscheduled readmission within 14 days of discharge for the same or related neurological condition.

(i) Death following an unscheduled admission from VA nursing home unit, domiciliary, transfer from a state or community nursing home or from a VA medical center with a major psychiatry mission to a Neurology Service in a VA medical center with a general medical and surgical mission.

(5) **Additional Categories Targeted for Autopsy**

(a) Deaths with medicolegal significance. Certain deaths which occur in a medical center will be of potential medicolegal significance. These deaths may be called Medical Examiner or Coroner's cases, in that they must be reported to a local investigatory agency. If the report of a death is made to the local investigatory agency of jurisdiction

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and the remains are waived back to the medical center, an autopsy may, and indeed should be, performed on the remains providing WRITTEN CONSENT IS OBTAINED FROM THE NEXT OF KIN. Cases which are considered of medicolegal significance include, but are not limited to:

1. Unnatural or violent death, whether due to suspected accident, homicide, suicide or undetermined means.

2. Death directly or apparently attributable to prior military duties.

3. Death related to vehicular, aircraft or vessel accidents.

4. Sudden death not caused by readily recognizable disease.

5. Death due to disease which may constitute a hazard to the public health.

6. Death occurring within 24 hours of invasive diagnostic or therapeutic procedures.

7. Death due to known or suspected therapeutic misadventure.

8. Death due to suspected negligence, incompetence or criminal activity of any staff member. (Ref. M-2, pt. VI, ch. 4, par. 4.05e(6).)

(b) The following are additional groups that could yield valuable findings at autopsy. These include veterans known to have been prisoners of war; those who served in Vietnam, alleged to have been exposed to agent orange; and, those exposed to radiation during atom bomb detonation in Hiroshima and Nagasaki.

(c) Strong clinical staff interest and support are mandatory for success in a program structured to anticipate a high autopsy rate among designated patient categories such as those identified.

8.04 PERFORMANCE OF AUTOPSY EXAMINATIONS

a. A complete clinical record and a listing of clinical questions or concerns related to possible autopsy findings will be furnished to the pathologist prior to beginning the autopsy.

b. Autopsy examination constitutes one aspect of the practice of medicine and will be performed by a qualified, licensed, physician, normally a

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pathologist credentialed and qualified in anatomic pathology. Some of the activities may be delegated to suitably trained allied health personnel only under the direct, personal supervision of a qualified pathologist. Members of the house staff who perform autopsies will also be under the direct supervision of a pathologist.

c. There will be positive identification of the deceased by the physician who will perform the autopsy before the procedure is actually begun. Such identification will consist of checking the name and other identifying data attached to the deceased and comparing these with information recorded on SF 523, Authorization for Autopsy. If there is uncertainty regarding identification, a physician or nurse who knew the deceased during life will make the necessary identification.

d. There will be strict adherence to the family's wishes as recorded on the SF 523, Authorization for Autopsy.

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e. The pathologist will notify the attending physician as soon as possible, as to the time of autopsy, and will arrange to demonstrate the gross findings.

f. Embalming prior to autopsy, whether by arterial injection or by intracavitary trocar injection, is prohibited because of the risk of these procedures causing anatomic alterations, making it impossible to determine if these changes preceded embalming. Care must be exercised that there is no undue delay in performing the autopsy which would inconvenience the family of the decedent.

g. Universal precautions as recommended by Centers for Disease Control will be vigorously enforced for preventing transmission of blood borne infectious diseases including AIDS, tuberculosis and hepatitis B. Other current recommendations from the Centers for Disease Control and the Food and Drug Administration for protecting health care workers will be followed. Current authoritative references should also be consulted for guidelines on protecting staff. All house staff, students, and other Laboratory Service personnel involved in autopsies on patients dying with blood borne infectious diseases, should follow universal precautions and be instructed on the epidemiology and modes of transmission of HIV-1 infection. Extreme care should be employed to prevent injury from needle sticks or from other sharp instruments contaminated with blood of an infected patient. If personnel encounter an accidental injury such as a cut or needle stick during an autopsy of a patient, the personnel should be evaluated clinically and serologically for evidence of HIV-1, hepatitis B or other infections as soon as possible after the exposure, and if seronegative for HIV-1, retested after 6 weeks, and on a periodic basis thereafter (i.e., 3, 6 and 12 months, following exposure to determine if transmission has occurred).

h. Autopsy examinations will be conducted in a professional manner. The objective of these examinations is the full exposition of the patient's disease processes, the limits thereof, and the patient's response to therapy. The body will be left in the best possible condition. Special examinations should be coordinated with appropriate funeral directors and VA authorities, as indicated. Authorization for removal of organ or tissue for donation is accomplished by completion of SF 523B, Authorization for Tissue Donation. (See par. 8.07).

i. Autopsy examination normally encompasses both gross and microscopic studies and sufficiently detailed protocol to meet the above objectives.

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Photographic documentation is an essential component of the autopsy examination and facilities should be readily available.

j. Autopsies on bodies of patients who have received certain therapeutic radioactive materials must be conducted with special precautions to safeguard personnel. In cases where the decedent has received such radioactive materials, the advice of the Radiation Safety Officer should be obtained.

(1) During all autopsies, disposable gloves and shoe coverings should be worn as well as gowns, masks and eye-coverings as noted in paragraph 8.04 g. Hands should be washed immediately if they become contaminated with blood. At the completion of the autopsy and after all instruments have been washed in soap and water, the instruments will be disinfected as recommended by the Centers for Disease Control, using any of the following:

(a) Hydrogen peroxide, 3 percent, from 5 to 10 minutes, or,

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(b) Sodium hypochlorite (house bleach) 1/10 dilution, or

(c) If formalin is used, 10 minutes should be satisfactory.

The instruments should be thoroughly rinsed in tap water and dried before reuse. Sterilization of instruments can be accomplished by machine, or by hand-cleaning, by trained personnel wearing appropriate protective attire.

(2) Following an autopsy the tables and floors should be flushed clean with a sodium hypochlorite solution under adequate ventilation.

(3) Soiled linens for sterilization are collected and placed in a plastic bag and appropriately marked. Materials for disposal are also placed in an appropriately labeled biohazards bag.

8.05 AUTOPSY REPORTS

a. Provisional anatomic diagnoses will be forwarded to the chief of the appropriate clinical service and to Medical Administration Service for inclusion in the patient's medical record within 1 work day or 24 hours and telephoned to the patient's primary care physician. The Chief, Laboratory Service, is responsible for establishing and maintaining a system for coding diagnoses, thereby enabling retrieval and compilation of cases. Final autopsy diagnoses will be coded by employing a recognized system of coding, e.g., SNOMED (Systematized Nomenclature of Medicine) or SNOP (Systematized Nomenclature of Pathology). The system selected will be capable of retrieving diagnostic information as needed.

b. SF 503, Autopsy Protocol, will be completed as the face sheet on all cases. Recognizing that the usefulness of the autopsy report is related to its timeliness of submission, the completed autopsy with final copy of succeeding pages will be made a part of the patient's record within 30 days, unless exceptions for special studies are established by the medical staff. The format and extent of the gross and microscopic descriptions will depend upon local practices, but sufficient information will be included to support the diagnoses rendered on the SF 503, Autopsy Protocol.

c. The following format for the autopsy protocol is suggested as likely to correspond to clinical interest:

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(1) Clinical diagnosis,

(2) Final anatomic diagnoses including neuropathologic findings,

(3) Gross and microscopic findings, including clinical summary,

(4) Discussion to correlate clinical and postmortem information,

(5) Completion of quality assurance survey, and

(6) Draft of lay letter to next of kin if requested.

d. Only a qualified licensed pathologist, board certified in anatomic pathology, will provide a final written diagnosis for gross and microscopic autopsy findings. If a resident in pathology signs an autopsy report, it will be countersigned by a board certified anatomic pathologist.

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e. The Chief, Laboratory Service, will be responsible for providing data on autopsy findings to the clinical service chiefs for use in their systematic internal reviews. The autopsy quality assurance survey to be completed after each autopsy should satisfy this requirement. The Chief, Laboratory Service, will present autopsy findings at regularly scheduled mortality review conferences.

f. The original SF 503, Autopsy Protocol, with all succeeding pages, will be placed in the patient's medical record. A copy of the autopsy report will be retained in the Laboratory Service. Copies will accompany any of the SERA (Systematic External Review of Autopsies) cases forwarded to the Special Reference Laboratory for Anatomic Pathology at the Armed Forces Institute of Pathology, Washington, DC 20306-6000. (See M-2, Pt. VI, Ch. 4, "VA Special Reference Laboratory for Pathology at the Armed Forces Institute of Pathology, Washington, DC"). Further distribution of copies of the autopsy report within the facility will be determined locally. Comments sent to, or generated by the Special Reference Laboratory are not protected by 38 U.S.C. Section 3305, but may be protected by other confidentiality statutes (see par. 8.08).

g. The Chief, Laboratory Service, will provide the Chief of Staff a copy of the autopsy report in any case in which the autopsy findings raise the possibility of a claim against VA.

h. Autopsy findings may be disclosed upon receipt of proper authorization and in accordance with M-1, part I, chapter 9. In any case where there is the slightest indication of a potential claim, no action should be taken to release information without first consulting with the District Counsel.

8.06 QUALITY MAINTENANCE IN THE AUTOPSY SERVICE

Performance standards will be established by the Chief, Laboratory Service, at each medical facility to ensure the pathologists' skills are sufficient, that the autopsy is performed accurately, and that the autopsy report addresses the questions of clinical concern to the patient's physician.

a. The autopsy can be used as an outcome measure to assess clinical diagnostic accuracy. Thus the autopsy can be established as an integral part of a quality assurance program to provide continuing medical education for physicians and medical students. A program for quality maintenance in anatomic pathology encompasses both external and internal components.

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(1) The external VA quality assessment programs in autopsy pathology operate as the SERA program (Systematic External Review of Autopsies) and the VA/AFIP Histopathology Quality Assessment Program which covers both autopsy and surgical pathology (M-2, Pt. VI, Ch. 4, "VA Special Reference Laboratory for Pathology, at the Armed Forces Institute of Pathology, Washington, DC").

(2) An internal quality assurance program requires a mechanism which integrates the autopsy findings with the clinical diagnoses. The program should be designed as an open-ended on-going quality assurance operation capable of monitoring performance of both clinician and pathologist. (See par. 8.06 b.)

(3) Any program for quality maintenance in anatomic pathology should have the following components: Process control; quality assessment or a system for documented evaluation; and quality control or remedial action to correct identified problems.

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(a) Process Control. Process control is a mechanism for insuring proper identification of the medical record of the patient to be autopsied, proper identification of the decedent including release of body to funeral director, an autopsy permit properly signed by the next of kin, maintenance of specimen identity throughout processing, control of reagents and examination of gross and microscopic tissues by qualified individuals. The autopsy protocol should be reviewed for appropriateness of terminology and absence of typographical errors or inadvertent mistakes by the pathologist.

(b) Quality Assessment. The most important element in this component is an on-site system (internal quality control) for timely documented second review of autopsy microslides and protocol. Each VA medical center will have a procedure for selecting cases for second review by a qualified pathologist. If a disagreement between the initial and reviewing pathologist as detailed under b.(1) occurs, additional consultation must be obtained.

(c) Quality Control or Remedial Action. The process control and quality assessment procedures may identify defects in the autopsy service system. It is the responsibility of the Chief, Laboratory Service, to institute actions for correction, including additional training of staff and to document both the problems and the actions.

b. **Internal Quality Control; Mandated Second Review of Cases**

Commencing on the date of this policy, each Chief, Laboratory Service, or in the absence of a permanent Chief, the Chief of Staff, will assure that a second review of autopsy cases is performed promptly, on no less than a quarterly basis, for at least 10 percent of all autopsy cases diagnosed in that medical center. The Chief, Laboratory Service, at each VA medical center will establish the procedures to be followed in conducting a second review, and, in cases of disagreement, a third opinion should be obtained.

(1) The mechanism for selecting autopsy cases for review should ensure representation of those likely to have posed diagnostic problems such as tumors, or controversial cases where the pathologist's diagnosis was at variance with the surgeon's opinion. Review of a resident's diagnosis by a staff pathologist does not constitute a second review in this context. Each case selected for second review by the procedures described above will be recorded in a log book with notation as to agreement or disagreement between reviewers and actions taken. Remedial action will be documented in the log

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book. Results of the consultant pathologist's review of the case in instances of disagreement will be brought to the attention of the Chief, Laboratory Service, and Chairperson of the Tissue Committee. These records are not protected by 38 U.S.C. Section 3305. However, the minutes of these reviews by the Tissue Committee are protected by the statute.

(2) In VA medical centers with two or more pathologists, reviews could be arranged from within the staff and the reviewing pathologist should initial and date the autopsy report when there is concurrence with the diagnosis. In cases where there is disagreement, a third opinion should be obtained expeditiously either from local consultants such as qualified pathologists at an affiliated medical school or from the AFIP with the request for consultation.

(3) In VA medical centers with less than two pathologists, a documented second opinion should be available on all major autopsy diagnoses, including malignant neoplasms, from either local consultants, a readily accessible VA medical center, or the AFIP with

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request for consultation. All cases with a disagreement between the clinical and pathological diagnosis must be reviewed by a second qualified pathologist. The second reviewer will either make a signed and dated note on the laboratory copy of the autopsy report, or provide a separate comment for attachment to the laboratory file copy of the autopsy report and original autopsy report, as a part of the patient's medical record.

c. **Quality Assurance Survey for Autopsy Service**

Following the completion of each autopsy, the pathologist and the primary care physician will complete a quality assurance information sheet as part of the Quality Assurance Program for the Autopsy Service. A sample survey sheet adapted from Schned[1] is contained in Appendix 8A. This should be overprinted on VA Form 10-0114h or 10-0114i. It may be duplicated and used by VA medical centers or modified as appropriate for local needs and made part of the quality assurance program. A numeric code may replace the patient's name. The purpose of this survey is to provide selected autopsy information on a continuing basis for integration with the medical center's quality assurance program, thereby monitoring both the pathology and clinical services. If another format is to be used locally, it should include the following information:

(1) Underlying disease and cause of death.

(2) Premortem diagnoses (including all tissue diagnoses, i.e., biopsies, cytology, etc).

(3) Premortem clinical questions posed by the physicians who cared for the patient.

(4) Answers to above questions to the extent possible from the autopsy findings.

(5) All important unexpected findings.

(6) All discrepancies in pre- and postmortem diagnoses.

(7) Clinical significance of autopsy findings.

References to the medical literature is contained in Appendix 8B which provide examples of similar forms and their role in quality assessment programs. The

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collected data serve as a mechanism for medical audit to yield internal feedback on diagnostic accuracy and error rate.

d. **Use of Information from Quality Assurance Survey**

A periodic tabulation of major and minor discrepancies of autopsy findings from all autopsies taken from these surveys will be presented to the clinical service and to the Chief of Staff for discussion at regularly-scheduled meetings such as mortality conferences or organ review sessions, at least once each quarter as specified by 38 CFR 17.507 (a)(4)(xi). These sessions will constitute a self-examination or internal review process. The records of these sessions are confidential, privileged and restricted in redisclosure, with financial civil penalties for violation. These records will be maintained in accordance with VA Regulation 17.527 and will not be retrieved by personal identifiers. All such records will be stamped as so identified and protected by 38 U.S.C Section 3305, in accordance with VA Regulation 17.521(b).

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e. **Disposition of the Quality Assurance Survey**

Since the survey serves as an internal monitoring function and may not be filed and retrieved by a personal identifier, these forms and information contained therein will not become part of the medical record. Rather they will be maintained in a separate quality assurance protected file 38 CFR Section 17.507(a)(4)(xi), so that they will be a part of the medical center's quality assessment program.

8.07 AUTOPSY TISSUES FOR DIAGNOSTIC, SCIENTIFIC OR THERAPEUTIC PURPOSES

SF 523, Authorization for Autopsy, makes provision for the removal and retention of tissues for diagnostic, scientific or therapeutic purposes. If the autopsy procedure is to include the removal of tissues not covered by permits in the VA medical center, a SF 523-b, Authorization for Tissue Donation, must be executed by the person authorized to grant permission for autopsy.

a. Special permission must be obtained for removal of organs and tissues for transplantation in accordance with M-2, Part XIV, Chapter 7, "Renal Disease Treatment Program - Transplantation."

b. M-3, Part I, Chapter 9, "Ethics, Confidentiality and Clinical Research," mandates that research using tissues or organs removed at autopsy will be in conformity with a written protocol approved by the local R&D (Research and Development) Committee and by its Subcommittee on Human Studies, before the research begins (par. 9.02f). When approved, that protocol will contain guidance for VA personnel concerning autopsy tissues used in research.

8.08 CONFIDENTIAL TREATMENT OF AUTOPSY RECORDS

If tissues or records are to be sent from VA for examination in non-VA laboratories or investigators, such persons can be given access to such items only within the restrictions imposed by laws governing the disclosure of information, e.g., the Privacy Act of 1974, 38 U.S.C. Sections 3301, 3305 and 4132.

a. Some of these statutes address the disclosure of information about patients in an individually identifiable format. If the examiner requires that the slides and records contain veterans' names or other confidential

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information, there must be a prior written agreement that the recipient of the slides and records will not redisclose any information in an identifiable form without prior specific VA authorization; that the information will be safeguarded from disclosure; and that the slides and records will be returned to VA when there is no longer a need for the recipient to retain them in order to accomplish the purpose for which they were originally supplied.

b. To the extent that any of the records discussed in this chapter are medical quality assurance records subject to 38 U.S.C. 3305 and its implementing VA Regulations, 38 CFR Sections 17.500-17.540, they may be disclosed only in accordance with the statute and VA Regulations.

c. When it is necessary to release records or slides in a manner other than that discussed above, the District Counsel should be consulted prior to the release.

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8.09 RETENTION OF AUTOPSY MATERIALS

a. The Laboratory Service copies of autopsy reports will be disposed of in accordance with VHS&RA Records Control Schedule 10-1. Binding in book form or storing on laser discs is strongly encouraged. RCS 10-2 provides disposition instructions for paper records only. Disposition approval for laser disc storage must be obtained. The Chief, Laboratory Service, will ensure appropriate retention and disposal of anatomic pathology materials as follows:

(1) Wet tissue will be retained only so long as it serves a useful purpose.

(2) A set of representative paraffin blocks will be retained for at least 5 years. They may be retained longer at the discretion of the pathologist provided there are suitable storage facilities. In cases with only one representative block of tissue, the block will not be used for quality control procedures.

(3) A set of stained microscope slides representative of each autopsy case will be retained indefinitely and stored to remain available for reference. VA retention periods for wet tissue, slides and blocks may vary from those suggested by the CAP (College of American Pathologists). VA retention periods will be followed rather than those of the CAP.

b. Specimens may be retained after completion of the autopsy and presented at conferences. Cases with unusual findings may be sent to the Armed Forces Institute of Pathology in accordance with M-2, part VI, chapter 4 as part of the SERA/SERS program.

c. Use of photographs to record gross and microscopic features is encouraged. Files of photographs including electron micrographs will be retained as long as they are considered to be useful.

d. Museum specimens and autopsy materials retained for authorized research projects or organized teaching collections may be exempted from the retention provisions.

8.10 AUTOPSY SUITE

a. Each VA medical center will have a properly equipped autopsy suite commensurate with local needs. There will be satisfactory ventilation, temperature control and good lighting.

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b. There will be sufficient refrigerated holding space to accommodate autopsy specimens. The temperature of the refrigerated holding area will be monitored by a recording thermometer which will be checked daily (a.m.) by facility personnel.

c. Equipment will include autopsy table(s), with necessary attachments, lifting devices, necessary instruments, scales, facilities for disinfection, X-ray viewing boxes, photographic and dictating equipment, and equipment to collect specimens for toxicological and microbiological studies.

d. There will be arrangements for proper disposal of discarded material.

e. Autopsy tables, instruments and non-disposable clothing will be cleaned and disinfected after the completion of each autopsy examination.

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f. The autopsy suite will be maintained in a clean and sanitary condition.

g. The specific infection control policies and procedures applicable to the autopsy suite will be reviewed by the Infection Control Committee at least annually.

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SAMPLE OF

AUTOPSY QUALITY ASSURANCE SURVEY

(To be completed by pathologist and clinician)

This document (or information contained herein) is deemed CONFIDENTIAL AND PRIVILEGED under provisions of 38 U.S.C. 3305. This material shall not be transmitted to anyone without proper consent or other authorization as provided by law or regulation.

PATIENT'S NAME _____
SERVICE _____
SOCIAL SECURITY # _____
CLINICIAN _____
VAMC _____
AUTOPSY NO _____
PATHOLOGIST _____
DATE _____

I. Postmortem Pathologic Diagnoses II. Clinical Premortem Diagnoses

_____
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III.
CLINICAL SIGNIFICANCE OF AUTOPSY
Comment or Check Appropriate

FINDINGS:
Category

a. Major disagreement in diagnosis
_____

b. Major unsuspected or additional

diagnosis
_____

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c. Significant clarification of differential diagnosis but no major disagreement:

_____

(1) Diagnosis suspected but not confirmed

_____

(2) Diagnosis among 2 or more equally considered

_____

d. Confirmation or verification of major diagnosis

_____

e. Autopsy indeterminate; does not clarify or resolve major issue

_____

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Comments

IV. Clinical Factors Related to or Contributing to Cause of Death (Check where applicable)

a. Unremitting course of disease

b. Error in judgment or treatment plan

c. Result of complication or therapeutic procedure

d. Unrecognized diagnosis with premortem evidence which existed by:

1. Physical exam

2. Patient complaint or symptom

3. Clinical course

4. Inattention to or misinterpretation

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_____
of diagnostic tests

_____
e. Other

V. Summary comment

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Adapted from Schned, AR, Mogielnicki, RP, Stauffer, ME: A Comprehensive Quality Assessment Program on the Autopsy Service. Am J. Clin. Pathol. 1986:86: 133-138

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